

Application Serial No. 09/996,977
Amendment dated: October 22, 2004
Reply to Office Action dated May 4, 2004

REMARKS AND ARGUMENT

The Official Action dated May 4, 2004 has been carefully studied. The Official Action raises several issues. In response, the claims are resubmitted without amendment for reconsideration.

The major issue raised in the Official Action is the rejection of all the claims under 35 U.S.C. § 103 with Williams as the principal reference. Reconsideration is requested. Williams, at column 4, lines 45-47, describes flanges 44 as "Optional flanges 44 are provided on members 18, 20 to facilitate the manual manipulation of thereof within the bag by the user, and to support the bag walls." When considering the Williams invention as a whole, the need for optional flanges to assist in the manipulation of the connector members 18 and 20 is not surprising. Williams is a two-piece connector system relying on two nesting conical structures. Manipulation of the connectors manually to ensure accurate positioning of the bag structures between the conical walls before irradiation is required and the flanges 44 are taught to assist in such positioning. Applicant's independent claims 1 and 7 require that the flange be positioned intermediate the two ends of a connector and that the bag be attached to the flange to maintain sterility of one end of the connector. The flanges 44 of Williams are positioned at the ends of the cones 18, 20 and the bag is not attached to the flanges but is supported by them. The lack of attachment in Williams means that sterility cannot be maintained by merely "supporting".

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Therefore, contrary to the Examiner's assertion, Williams does not "disclose the claimed invention with the exception that his connector comprises two pieces." The flange is not intermediate and the bag is not attached. A further clear difference between Applicant and Williams is that in order for the Williams invention to operate, the connector must be free floating inside the bag prior to making a connection, and both ends of the funnel's fluid conduit must be enclosed and inside the pouch in order for sterility to be maintained. It is also not understood as to how the Williams invention could function as a "one-piece" structure since the art of the Williams invention clearly teaches that the two funnel structures and the bags are both a requirement of their operation and intended to work together. Half of the Williams invention, i.e. one bag and one funnel, contain vastly different key elements of their structure when compared to the applicant's invention as stated above. The Examiner's view that applicant claims a "one piece" version of Williams' "two piece" structure ignores the fact that modification of Williams to achieve the Examiner's stated "obvious" result required a complete abandonment of Williams structure and function.

Regarding the claimed limitations of "intermediate" and "attached", attention is again invited to M.P.E.P. § 2111.01 which provides in part:

"PLAIN MEANING" REFERS TO THE MEANING GIVEN TO THE TERM BY THOSE OF ORDINARY SKILL IN THE ART

When not defined by applicant in the specification, the words of a claim must be given their plain meaning. In other words, they must be read as they would be interpreted by those of ordinary skill

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in the art. >*Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001)(explaining the court's analytical process for determining the meaning of disputed claim terms); *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)(“[W]ords in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning.”). See also <*In re Sneed*, 710 F.2d 1544, 218 USPQ 385 (Fed. Cir. 1983) (The applicants had argued in an amendment after final rejection that the term “flexible plastic pipe,” as used in the claims, pertained only to pipes of 2-inch diameter and 3-inch diameter and not to a pipe of 1.5 inch diameter. This definition of “flexible” was also advanced in an affidavit. The prior art, however, described 1.5 inch pipe as flexible. The court held that the specification and the evidence (the prior art) failed to support the gloss appellants sought to put on the term “flexible.” Note that applicant had not defined “flexible plastic pipe” in the specification.); *In re Barr*, 444 F.2d 588, 597, 170 USPQ 330, 339 (CCPA 1971) (“The specification in this case attempts no definition of the claim language ‘a phenyl radical.’ Accordingly we must presume that the phrase was used in its commonly accepted technical sense....[Applicants] have not referred us to any standard work on chemistry which indicates that the commonly accepted technical meaning of the words ‘a phenyl radical’, without more, would encompass the hydroxyphenyl radical. On the contrary, Hackh’s [Chemical Dictionary] quite plainly defines ‘phenyl’ as ‘the monovalent radical... derived from benzene... or phenol.’”).

The rejection of claims on Williams ignores these claimed limitations.

Similar logic applies in the rejection of claims 2, 7, and 10-11 on Williams and Niedospial in paragraph 3 of the Official Action. What purpose would be served or function produced if the shape of the flanges 44 of Williams were changed in the manner proposed by the Examiner? Niedospial does not show or suggest the claimed configurations. The rejection relies on applicant's teachings of the claimed configuration of the flange.

Niedospial teaches a “Multiple Use Universal Connector” for fluid bags as an integral part of the bag with a re-enterable, self-sealing diaphragm so that a pharmaceutical fluid contained in the container can be repeatedly accessed. This invention is designed to

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be an integral part of the fluid container and contains a diaphragm for use with a needle, cannula or Luer type syringe. There is no provision for tubing connections on the inside of the fluid chamber as it is not a desired feature or intention of the Niedospial invention. This makes it unsuitable to solve the problems described as a hose connector for BioProcess Containers.

The Examiner's suggestion that Williams be enclosed in an overwrap is not understood. Would the proposed overwrap enclose each piece of Williams' two-piece connector before nesting and irradiation, would the overwrap enclose the entire irradiated connected structure, or would the overwrap enclosed some portion of one piece of Williams' two-piece connector?

Similarly, the rejection of claims 3-4 on Williams alone in paragraph 4 of the official action proposes that the surface of flanges 44 be modified in shape. Reliance on *In re Dailey*, 357 F.2d 669 (1966) is misplaced. Before the holding of *Dailey* can be applied, all the elements of the claim must be found in the prior art. The claim requirements of "intermediate" and "attached" are not found in Williams.

The rejection of claims 5 and 12 on Williams and Heilmann, et al. in paragraph 5 of the Official Action should be withdrawn for the same reasons as discussed above in connection with their parent claims. The Examiner suggests that the difference between Williams and the claims concerning the connector end not enclosed by the overwrap be

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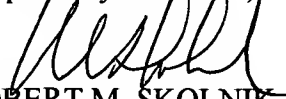
attached to a fluid processing bag. But such modification of Williams is without function or purpose in Williams. There is no need to protect the ends of the connectors in Williams as same are already fully enclosed by the respective bags in which the conical connectors are located.

Claim 6 was rejected on Williams, Heilmann, et al., and Niedospial. Again as discussed in connection with the rejection of claims 5 and 12, the modifications to Williams proposed by the Examiner have no function or purpose in Williams because the connectors are fully enclosed from start to finish. Each cone is manually manipulated into nesting contact, then radiation is applied to create the seal, then a fluid path is manually opened while at all times each connector is enclosed in the sterile field.

The rejections of dependent claims 13-15 as set forth in paragraphs 7 and 8 of the Official Action are traversed for the reasons advanced in connection with applicant's response to the rejections of the parent claims on which they depend.

Reconsideration and favorable action is respectfully requested. Should the Examiner deem the above arguments insufficient, Applicant suggests a personal interview be held before further action is taken in this application.

Respectfully submitted,



ROBERT M. SKOLNIK

Reg. No. 24,688

Attorney for Applicant

353 Monmouth Road, P.O. Box 22

October, 22, 2004

West Long Branch, N.J. 07764
(732) 222-1027

CERTIFICATE OF MAILING

I certify that all of these documents are being deposited with the United States Postal Service on October 22, 2004 in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Dated: October 22, 2004



ROBERT M. SKOLNIK